

REMARKS

As an initial matter, Applicant wishes to thank the Examiner for the courtesy of the telephonic interview conducted on September 22, 2006. A summary of the Interview is attached hereto as Exhibit A.

Claims 5 and 6 are currently pending in this application. All of the claims have been rejected. By this amendment, Applicant has amended claim 5 and added new claims 21 to 23. Full support for the amendments and new claims is found in the specification and drawings as filed. No new matter has been added. In view of the above amendments and the following remarks, Applicant respectfully submits that this application is in condition for allowance. Accordingly, a timely indication of allowance is respectfully requested.

The Present Invention

The present invention is directed to a novel and non-obvious method of breeding an animal line for experimental use.

As explained in the specification on page 2, line 12 to page 3, lines 22, laboratory mice are only allowed to breed for eight months. Over the last half century this has radically altered the telomeres of lab mice compared to wild mice. The telomeres of lab mice are typically ten times longer than the telomeres of normal mice. As a consequence, lab mice overwhelmingly die of tumors, show few signs of decline with age, have an extraordinary ability to regenerate tissue with age, and have an extraordinary ability to repair damage throughout life.

These differences have led to problems with current lab mice for use in testing drugs, pesticides and other chemical agents and procedures. For example, some substances that have been shown to cause cancer in lab mice, such as saccharin, seem to

produce no such effect in humans. Conversely, for example, some substances that are now suspected of causing tissue damage in humans, such as Fen-Phen (fenfluramine, phentermine, dexfenfluramine), did not cause enough harm to laboratory animals to raise appropriate safety questions.

Accordingly, as explained on page 4, lines 2 to page 6, line 3, breeders need to breed test animals in such a manner that laboratory tests can give researchers an accurate picture of the probable risks, costs, hazards and dangers that humans, pets and other species are likely to face when exposed to the agents and procedures being tested. In order to accomplish this end, the present invention is directed to a method of breeding an animal line for experimental use comprising the steps of: preselecting a first population of one or more conspecific animals comprising cells comprising chromosomes with telomeres of determinable lengths; determining a statistical distribution of telomere lengths among cells of the animals of the first population; and following the determining step, permitting animals with a desired distribution of telomere lengths to produce offspring. By controlling the distribution of telomere lengths in test animals using the method of the present invention, researchers can get more accurate test results.

Claim Amendments and New Claims

Claim 5 has been amended to state "following the determining step, permitting a subset of the first population having telomere lengths greater than a median telomere length or a subset of the first population having telomere lengths less than the median telomere length to produce offspring." Claim 21 specifies that the subset of the first population permitted to produce offspring has telomere lengths greater than the median telomere length of

the first population. Claim 22 specifies that the subset of the first population permitted to produce offspring has telomere lengths less than the median telomere length of the first population. New claim 23 recites "following the determining step, excluding a subset of the first population from producing offspring, the subset comprising animals with telomere lengths outside of a predetermined range of telomere lengths."

Full support for the amendments to claim 5 and new claims 21 to 23 is found in the specification and drawings as filed, for example, on page 5, lines 5 to 13 and on page 5, line 19 to page 6, line 3. No new matter has been added. Applicant respectfully requests that the above amendments be entered and considered by the Examiner.

Rejections Under 35 U.S.C. §102(b)

The Examiner rejected claims 5 and 6 under 35 U.S.C. §102(b) as being anticipated by Lee et al. (Nature 329:669-674). In view of the amendments to claims 5 and 6, Applicant respectfully traverses this rejection.

Claim 5, as amended, requires the steps of: "determining a statistical distribution of telomere lengths among cells of the animals of said first population; and following the determining step, permitting only a subset of the first population having telomere lengths greater than the median telomere length or a subset of the first population having telomere lengths less than the median telomere length to produce offspring." Applicant respectfully submits that Lee et al fail to teach or suggest either of these limitations.

Lee et al. are directed to a study of the role of mouse telomerase in highly proliferative organs. As part of their experimentation, Lee et al. produced additional generations of

mice from successive matings. (See pg. 570). Once produced, all of the generations of mice were analyzed for differences. However, no determination of a statistical distribution of telomere lengths was made prior to breeding as required by claim 5. Moreover, breeding was not limited to a subset of the animals having telomere lengths greater than a median telomere length or a subset of the first population having telomere lengths less than the median telomere length, as also required by claim 5. A requirement of the experimental methodology of Lee et al. was that they not breed selectively according to telomere length. Had they done so, then it would not have been a valid test of their hypothesis. Therefore, Lee et al. do not anticipate claim 5.

Additionally, one skilled in the art would have no motivation to modify Lee et al. to determine a statistical distribution of telomere lengths prior to breeding or to limit breeding to those animals with a desired distribution of telomere lengths as claimed, because Lee et al. were not concerned with achieving a test animal population suitable for testing drugs, pesticides and other chemical agents and procedures. Rather, Lee et al. focused on effects of the absence of mouse telomerase over subsequent generations. Accordingly, Applicant respectfully submits that claim 5, as amended, is patentable over Lee et al.

Claim 6 and new claims 21 and 22 are dependent on claim 5 and by definition contain all of the limitations of claim 5. Therefore, claims 6, 21 and 22 are patentable over Lee et al. for the reasons given above for claim 5 as well as because of the additional limitations contained therein. Accordingly, Applicant respectfully requests that the 35 U.S.C. §102(b) rejection of claims 5 and 6 based on Lee et al. be withdrawn. Additionally,

Applicant respectfully submits that new claims 21 and 22 are patentable over Lee et al.

New Claim 23

New claim 23 requires the steps of: "determining a statistical distribution of telomere lengths among cells of the animals of said first population; and following the determining step, excluding a subset of the first population from producing offspring, the subset comprising animals with telomere lengths outside of a predetermined range of telomere lengths." As explained above, Applicant respectfully submits that in Lee et al., no determination of a statistical distribution of telomere lengths was made prior to breeding and no animals were excluded from breeding based on telomere length as required by claim 23.

Accordingly, Applicant respectfully submits that new claim 23 is patentable over Lee et al.

CONCLUSION

In view of the above amendments and remarks, Applicant respectfully submits that this application is in condition for allowance. Accordingly, reconsideration and a timely indication of allowance are respectfully requested.

If the Examiner believes a telephone conference would aid in the prosecution of this application, the Examiner is invited to contact the undersigned at the below-listed telephone number.

A fee of \$395 for a Request for Continued Examination and a fee of \$225 for a two month extension of time are believed due with this communication. The Commissioner is hereby authorized

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to charge this fee and any additional fees due with this communication to Deposit Account No. 19-2090.

Respectfully submitted,

SHELDON MAK ROSE & ANDERSON

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By /Marc Karish/

Marc Karish

Reg. No. 44,816

SHELDON & MAK PC
225 S. Lake Avenue, 9th Floor
Pasadena, California 91101
(626) 796-4000